The representation of the sensibility of the breast on the somatosensory cortex using 7 Tesla fMRI: A pilot study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON46265

Source
ToetsingOnline

Brief title
fMRI-study somatotopy breasts

Condition

- Other condition

Synonym
Sensibility of the breast, the feeling of the breast

Health condition

Niet van toepassing, onderzoek bij gezonde proefpersonen

Research involving
Human

Sponsors and support

Primary sponsor: Plastische Chirurgie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Breast, Magnetic Resonance Imaging, Somatosensory cortex

Outcome measures

Primary outcome

The hemodynamic response after stimulation of the skin of the breast and nipple-areola complex, representing neuronal activity in that region, is measured. Within the somatosensory cortex (S1 and S2), the temporo-spatial brain activity patterns after the various stimulation conditions are assessed, and the representation of the breast on the somatosensory cortex is mapped.

Secondary outcome

The temporo-spatial brain activity patterns are studied, to assess whether there are differences in representation of the breast on the somatosensory cortex between subjects of the same sex, as well as whether there are sex-specific differences in representation.

Study description

Background summary

To explore the effects of mastectomy and autologous breast reconstructions, in which neurorrhaphy or nerve anastomosis has been performed, on the sensibility of the breast, the representation of the breast on the somatosensory cortex should be studied. This has not been done in previous studies. Before the aforementioned effects can be assessed in terms of neuroplasticity, the representation of the breast must be precisely located with the use of a 7 Tesla fMRI. Therefore, a pilot study with healthy subjects is needed to

localize the sensibility of the breast on the somatosensory cortex.

Study objective

To determine the exact localization of the representation of the sensibility of the breast and nipple-areola complex on the somatosensory cortex, in order to select a region of interest for upcoming studies. Secondly, to assess whether there are differences in representation between individuals of the same sex and between both sexes.

Study design

A single center pilot study carried out in MUMC+.

Study burden and risks

All subjects have one appointment at the outpatient clinic for a short (10-15 minutes) introductory visit. Extra information about the study and procedures is given, as well as the subject information and consent form. On a later moment every subject will undergo 90 minutes of fMRI scanning. There are no follow-up moments. In addition, there are no risks associated with participation, except for the MRI-related risks like vertigo, nausea, an anxious/claustrophobic feeling, and experiencing a taste of metal in the mouth upon entering the scanner. In fMRI is no radiation involved. Subjects do not have any benefits in participating in the study, except for the experience of brain mapping. In the rare case an anomaly is identified on any of the fMRI images, this will be discussed with the subject and this information is shared with the general practitioner. Subjects who are willing to participate in the study, accept the fact that vibrators are applied on a bare breast to stimulate the skin and nipple-areola complex. The burden associated with participation in this study, involves the usual MRI side effects (e.g. anxious or claustrophobic feelings) and a possible adverse skin reaction to adhesives upon applying the vibrators.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Man or woman
- Between 21 and 35 years old
- Healthy; i.e. no comorbidities
- Women: breast size cup B or C
- BMI < 27.0 kg/m2
- Informed consent

Exclusion criteria

- Any comorbidities
- Previous breast operation of any kind
- Previous allergic reactions to adhesives or plasters
- Any MRI exclusion criteria e.g.:
o (No piercings or other iron materials (except a metal brace behind front teeth)
o Claustrophobia)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-07-2016
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	23-12-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT02739646
CCMO	NL54890.068.15

Study results

Date completed:	17-01-2018
Actual enrolment:	20

Summary results
Trial is onging in other countries